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510(k) Summary

1. Date of Summary

October 16, 2009

2. 510(k) Applicant

NOV 17 2009

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3. Device Overview

Trade Name: LungPoint™ Procedure Planning Software

Common Name: Picture Archiving and Communications Systems

Classification Name: System, Image Processing, Radiological
21 CFR 892.2050
Product Code LLZ

4. Predicate Device

The predicate device identified for the LungPoint VBN is as follows:

Trade Name	510(k) Submitter	510(k) Number
LungPoint™ Virtual Bronchoscopic Navigation Software	Broncus Technologies, Inc.	K091160, cleared to market 5 May, 2009

5. Device Description

LungPoint Procedure Planning, a software only device. As with the predicate, it provides the physician with 3D reconstruction of the patient's lungs, derived from the CT images and thus provides a more realistic view of the lungs. The physician can use the 3D virtual animation and associated images to view and explore pre-selected targets in the lung tissue before conducting a procedure.

Like the predicate, the software allows for printing the procedure plan as a map, which consists of a bifurcation-by-bifurcation description of the route to the selected target.

The LungPoint Procedure Planning software is installed on an off-the-shelf PC computer, and is intended to be used in conjunction with commercially-available CT scan images that are saved in DICOM format.

6. Intended Use

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

7. Comparison to Predicate Device

The LungPoint Procedure Planning software version 2.0 has the same intended use, technological characteristics and hardware as the predicate's planning phase. Both products provide guidance to the physician and use the exact same software (including core algorithms) for planning. The key features: 3D animation and printable plan/map; are identical to those of the planning phase of the predicate device and the same software algorithms are used. The only difference is that the real-time navigation tools are removed from the Procedure Planning product.

The User Manual was updated to reflect the modifications.

8. Performance Data

The planned modifications were subjected to the Broncus design control process. Appropriate labeling changes, risk analysis, and design verification were performed to assure that the Procedure Planning software continues to meet its intended use.

9. Safety and Effectiveness

The LungPoint Procedure Planning labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the software. Risk management is ensured via a hazard analysis and FMECA, which are used to identify potential hazards. These potential hazards are controlled via software development, verification testing and/or validation testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Broncus Technology, Inc.
% Mr. Mark Job
Reviewer
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO, MN 55313

NOV 17 2009

Re: K093423
Trade/Device Name: LungPoint Procedure Planning Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communication Systems
Regulatory Class: II
Product Code: LLZ
Dated: November 2, 2009
Received: November 3, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093423

Device Name: LungPoint™ Procedure Planning Software

*Indications for Use: Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-CounterUse _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K093423

Concurrence of CDRH, Office of Device Evaluation (ODE)